DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 14, 2015

APEX BIOTECHNOLOGY CORP.
HSUE-MEI LEE
MANAGER OF QUALITY ASSURANCE DEPARTMENT
NO. 7 LI-HSIN ROAD V, HSINCHU SCIENCE PARK
HSINCHU, 30078, CHINA

Re: K150396
Trade/Device Name: AutoSure Voice II Blood Glucose Monitoring System
AutoSure Voice II Pro Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: September 11, 2015
Received: September 14, 2015

Dear Hsue-Mei Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k150396

Device Name
AutoSure Voice II Blood Glucose Monitoring System

Indications for Use *(Describe)*

The AutoSure Voice II Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. The meter includes voice functionality to assist visually impaired users. It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitoring blood glucose levels in diabetes mellitus. This system is for single-patient use only and should not be shared. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). It is not intended for the diagnosis or screening of diabetes or for neonatal use.

The AutoSure Blood Glucose Test Strips are to be used with the AutoSure Voice II Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k150396

Device Name
AutoSure Voice II Pro Blood Glucose Monitoring System

Indications for Use *(Describe)*

The AutoSure Voice II Pro Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. The meter includes voice functionality to assist visually impaired users. It is intended for multiple-patient use in professional healthcare settings as an aid in monitoring blood glucose levels in Diabetes Mellitus. This system should only be used with single-use auto-disabling lancing devices. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). It is not intended for the diagnosis or screening of diabetes or for neonatal use.

The AutoSure Pro Blood Glucose Test Strips are to be used with the AutoSure Voice II Pro Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

Submitter	Hsue-mei Lee Manager of Quality Assurance Department Apex BioTechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park, Hsinchu, 30078, CHINA (TAIWAN) email: hsue-mei@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678302
Contact Person	Hsue-mei Lee Manager of Quality Assurance Department Apex BioTechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park, Hsinchu, 30078, CHINA (TAIWAN) email: hsue-mei@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678302
Date Prepared	October 12, 2015
Trade Names	AutoSure Voice II Blood Glucose Monitoring System AutoSure Voice II Pro Blood Glucose Monitoring System
Classification	Glucose test system, 21 CFR 862.1345, Class II
Product Codes	CGA, NBW
Predicate Device	AutoSure Voice II Blood Glucose Monitoring System and AutoSure Blood Glucose Test Strips (k102037)
Device Description	The AutoSure Voice II Blood Glucose Monitoring System consists of the AutoSure Voice II Meter and AutoSure Blood Glucose Test Strips. It is used for testing of blood glucose by self-testers at home. The AutoSure Voice II Pro Blood Glucose Monitoring System consists of the AutoSure Voice II Pro Meter and AutoSure Pro Blood Glucose Test Strips. It is used for testing of blood glucose by professional testers in healthcare facilities. The AutoSure Voice II and AutoSure Voice II Pro systems are identical other than trade names and details of product labeling.

510(k) Summary (Continued)

Intended Use	The AutoSure Voice II Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. The meter includes voice functionality to assist visually impaired users. It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitoring blood glucose levels in diabetes mellitus. This system is for single-patient use only and should not be shared. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). It is not intended for the diagnosis or screening of diabetes or for neonatal use. The AutoSure Blood Glucose Test Strips are to be used with the AutoSure Voice II Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. The AutoSure Voice II Pro Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. The meter includes voice functionality to assist visually impaired users. It is intended for multiple-patient use in professional healthcare settings as an aid in monitoring blood glucose levels in Diabetes Mellitus. This system should only be used with single-use auto-disabling lancing devices. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). It is not intended for the diagnosis or screening of diabetes or for neonatal use. The AutoSure Pro Blood Glucose Test Strips are to be used with the AutoSure Voice II Pro Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm.
Comparison of Technological Characteristics	The modified AutoSure Voice II and AutoSure Voice II Pro Blood Glucose Monitoring Systems are identical to the original (predicate) system other than a) separation of the self-testing and professional usage claims into two products and b) the recommendation of four additional disinfectants in the User's Guides.
Non-Clinical Testing	Disinfection (viral inactivation) and "robustness" testing were done to qualify all recommended disinfection solutions. Results demonstrate substantial equivalence to the original (predicate) device.
Clinical Testing	No clinical testing was conducted.
Conclusion	Testing showed that the modified AutoSure Voice II and AutoSure Voice II Pro Blood Glucose Monitoring Systems are substantially equivalent to the original (predicate) system.